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EXAMINER	
LEE, SHUN K	

ART UNIT	PAPER NUMBER
2884	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,457	CASPERSEN, CHRISTIAN	
	Examiner	Art Unit	
	Shun Lee	2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,9,11,12,15,16,23-25,27-29,36,37,40 and 44-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,9,11,12,15,16,23-25,27-29,36,37,40 and 44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 December 2005 has been entered.

Claim Objections

2. Claim 11 is objected to because of the following informalities: "claim 10" on line 1 in claim 11 should probably be --claim 1--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 7, 9, 11, 12, 15, 16, 23-25, 27, 28, 40, 44, 45, 46, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification (pg. 14, lines 27-30) disclose that " ... the scanning control means may be adapted to place an automated microscope at the position of any desired target object. Thereby, a medical doctor or a laboratory technician is capable of performing a detailed examination of the target object to e.g. establish its identity". However, applicant has not pointed out where the amended claim is supported, nor does there appear to be a written description of the claim limitation "a microscope for ... recording images of the marked objects" in the application as filed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 recites the limitation "wherein identify of the marked objects is establishable by viewing the images of the marked objects" which fails to particularly point out what particular apparatus structural limitation is required by an identity establishable from viewing of images of the marked objects presumably by a user of the apparatus.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 7, 9, 11, 12, 27, 29, 36, 37, 40, 44, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber *et al.* (US 6,110,748) in view of Gordon (US 5,892,577) and Virtanen (US 6342349).

In regard to claims **1**, **46** (in so far as understood), and **48**, Reber *et al.* disclose (Fig. 1) an apparatus for detecting a property of marked object contained in a specimen, the apparatus comprising:

(a) a frame (is inherent in positioning mechanism 42; column 4, lines 17-28);

(b) a member (20) positioned on the frame and having a surface that is adapted to receive and hold the specimen (column 2, line 28 to column 3, line 7);

(c) at least a first light source is inherent for emitting at least a first light beam towards the specimen held by the member (20) since fluorescence (see *e.g.*, fluorescent members; column 3, lines 43-47) is defined[1] as the "emission of electromagnetic radiation, especially of visible light, stimulated in a substance by the absorption of incident radiation and persisting only as long as the stimulating radiation is continued";

(d) at least a detector (38) for detecting a light (*i.e.*, fluorescence) emitted from the marked objects (*i.e.*, fluorescent members; column 3, lines 43-47) upon interaction with the first light beam;

(e) scanning means (42) for scanning the specimen in relation to the detector (38) along a non-linear curve (*e.g.*, spiral 152 in Fig. 12), wherein the scanning means

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comprises means (*i.e.*, rotary positioning mechanism; column 4, lines 17-28; column 9, lines 37-40) for rotating the member and means (*i.e.*, translational positioning mechanism; column 4, lines 17-28; column 9, lines 37-40) for displacing the member, so as to detect the property of the marked objects in the entire specimen, the means for rotating and the means for displacing being directly connected to the member (*i.e.*, a rotary positioning mechanism such as a spindle or a turntable, a translational positioning mechanism such as a conveyor, and/or a multiple degree of freedom positioning mechanism such as a robotic arm; column 4, lines 17-28), the member being rotatable and displaceable (*i.e.*, the step of positioning at least one of the device 20 and the detector 38 can include translating the device 20, rotating the device 20, translating the detector 38, and/or rotating the detector 38; column 9, lines 37-40); and

(f) scanning control means (*e.g.*, processor 36) for controlling the scanning means (42) for scanning the specimen along the non-linear curve (column 5, lines 1-9).

While Reber *et al.* also disclose (column 3, line 56 to column 4, line 10) to provide an apparatus comprising a detector 38 and (column 5, lines 1-9) that the positioning mechanisms are operated to collect data in a sequential manner from sites along annular (*e.g.*, circular 140 in Fig. 11) or spiral (*e.g.*, spiral 152 in Fig. 12) tracks (column 3, lines 5-7), the apparatus of Reber *et al.* lacks a means for retrieving position signals such as angular and radial coordinates from a storage means wherein the scanning control means uses the retrieved position signals to place a microscope for viewing (*i.e.*, optical inspection) or recording images at the position of the marked objects to allow a

user to view the images of the marked objects via the microscope so as to establish identity wherein the position signals stored in the storage means correspond to marked object detector signals stored in the storage means and that the first light source and the detector are arranged so that a part of a light beam path from the first light source to the specimen is co-axial with a part of the light emitted from the marked objects with the member displaced along a radius of the member rotation. First it should be noted that a spiral track is generated by relative translation along a radius of the rotary movement. Further, Gordon teaches (column 5, lines 28-31 and 64-67; column 8, lines 15-56; Fig. 1) a light beam path from a light source (8) to disc (1) that is co-extensive with a part of the light from the disc (1) to a detector (11) wherein the detected signal data are transferred to a computer via a means for sampling and digitizing the signals and that the detected object positions stored in a storage means are retrieved and used by a scanning means to position a means for optical inspection of detected objects (*i.e.*, "look again at specific region of interest"; column 5, lines 58-62; column 6, lines 4-10 and 19-32; column 7, line 55 to column 8, line 27) and how to precisely determine the angular position and the radial position (column 9, lines 15-23). In addition, Virtanen teaches (column 48, lines 41-63) that with proper software, optical disk readers are scanning confocal laser microscopes which allow the study and identification of the detailed structure of biological and other specimens (*e.g.*, to detect several different cell types). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a conventional epifluorescence microscope (having a conventional optical arrangement wherein a light beam path from a light source to

specimen is co-extensive with a part of the fluorescence emitted from the specimen) and conventional means for sampling and digitizing detector and position signals in the apparatus of Reber *et al.*, in order to obtain data from measurements of specimens along annular or spiral tracks by relative translation along a rotational radius suitable for storage and processing on a conventional computer with the capability to look at images of specific regions of interest (*e.g.*, any desired target object) located at precisely determined angular and radial coordinates so as to identify several different types of cells.

In regard to claims **29**, **47**, and **49**, the method steps are implicit for the modified apparatus of Reber *et al.* since the structure is the same as the applicant's apparatus of claims 1, 46, and 48.

In regard to claim **7** which is dependent on claim 1, Reber *et al.* also disclose (column 4, lines 17-28) that the member is positioned for rotation about an axis on the frame and wherein the means for rotating the member rotates the member about the axis.

In regard to claim **9** which is dependent on claim 1, Reber *et al.* also disclose (column 5, lines 1-9) that the scanning control means (*e.g.*, processor 36) are adapted to control the scanning means in such a way that the non-linear curve is a substantially circular curve (*e.g.*, circular 140 in Fig. 11).

In regard to claim **11** (which is dependent on claim 10) and claim **37** (which is dependent on claim 36), while Reber *et al.* also disclose (column 3, lines 56-60; column 4, lines 4-10) a CD-ROM or DVD reader which provides signals for processing by a

processor such as a computer (column 5, lines 1-22), the apparatus of Reber *et al.* lacks an explicit description of means for sampling and digitizing the detector signals and the position signals. Gordon teaches (column 8, lines 15-56) to transfer detected signal data to a computer via a means for sampling and digitizing the signals. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a means for sampling and digitizing the detector signals and the position signals in the apparatus of Reber *et al.*, in order to convert the data to a form suitable for processing by a computer.

In regard to claim **12** which is dependent on claim 1, Reber *et al.* also disclose (column 5, lines 1-22) signal processing means (*e.g.*, processor 36) operatively connected to the detector (38) to detect a presence of an object based on the detector signals.

In regard to claim **27** which is dependent on claim 1, while Reber *et al.* also disclose (column 3, lines 56-60; column 4, lines 4-10) a CD-ROM or DVD reader, the apparatus of Reber *et al.* lacks an explicit description that the CD-ROM or DVD reader comprises a coherent light source. However, CD-ROM (*i.e.*, compact discs) readers are well known in the art. For example, Gordon teaches (column 5, lines 28-31 and 64-67) that a conventional compact disc reader comprises a coherent light source. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that the detector (*e.g.*, a CD-ROM reader) in the apparatus of Reber *et al.* comprises a coherent light source.

In regard to claim **36** (which is dependent on claim 29), Reber *et al.* also disclose (column 5, lines 58-62) storage means (*e.g.*, memory 49 or device 20) for storage of detector signals (related to the detected property) provided by the detector (38) and corresponding position signals (related to the current position of the member) provided by the scanning control means.

In regard to claim **40** which is dependent on claim 1, Reber *et al.* also disclose (column 3, lines 39-47) that the marked objects are marked with a fluorescent stain.

In regard to claim **44** which is dependent on claim 1, the apparatus of Reber *et al.* lacks that the detector comprises a CCD device. Gordon teaches (column 10, lines 7-19) to provide a CCD device for scanning a disc in order to obtain higher speed and higher resolution. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a CCD device as the detector in the apparatus of Reber *et al.*, in order to obtain higher speed and higher resolution.

9. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber *et al.* (US 6,110,748) in view of Gordon (US 5,892,577) and Virtanen (US 6342349) as applied to claim 1 above, and further in view of Demers (WO 98/12559).

In regard to claims **15** and **16** which are dependent on claim 1, while Reber *et al.* also disclose (column 7, lines 59-62) a member such as a standard CD-ROM to receive and hold the specimen, the modified apparatus of Reber *et al.* lacks that the specimen has an area larger than 500 mm^2 (*e.g.*, larger than 8000 mm^2). However, standard CD-

ROMs (*i.e.*, compact discs) are well known in the art. For example, Demers teaches (pg. 5, third paragraph) that a compact disc is a 5.5 inch disc. A ~15328 mm^2 area has a diameter of ~140 mm (5.5 inch). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that the ~15328 mm^2 area (*i.e.*, standard CD-ROM sized) member in the modified apparatus of Reber *et al.* is capable of receiving and holding specimens of ~15328 mm^2 area or less (*e.g.*, larger than 500 mm^2 or 8000 mm^2).

10. Claims 23-25, 28, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber *et al.* (US 6,110,748) in view of Gordon (US 5,892,577) and Virtanen (US 6342349) as applied to claims 1 and 40 above, and further in view of Ekins *et al.* (Multianalyte microspot immunoassay-microanalytical "compact disk" of the future, Clinical Chemistry, Vol. 37, no. 11 (1991), pp. 1955-1967).

In regard to claims **23-25** which are dependent on claim 1, the modified apparatus of Reber *et al.* lacks that a mask is inserted in the optical path between the specimen and the detector, wherein the mask comprises at least one transparent aperture having a substantially rectangular shape with at least one dimension of the aperture, as projected on the specimen, between 0.75 and 2 times the dimensions of objects to be detected. Ekins *et al.* teach (left column on pg. 1964) that the highest signal/noise ratio is observed when the instrument field of view is restricted to a microspot area. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aperture in the modified apparatus of Reber *et al.* to restrict the field of view to substantially a microspot area (*i.e.*, matching

size and shape), in order to detect fluorescent members with a desired signal/noise ratio.

In regard to claim **28** which is dependent on claim 1, the modified apparatus of Reber *et al.* lacks that the first light beam is adapted provide a light spot having a diameter between 20-150 μm on the specimen. Ekins *et al.* teach (left column on pg. 1963) that as the area decreases, the signal/noise ratio increases and approaches a maximum value of 60 as the area falls below 0.01 mm^2. A 0.01 mm^2 area has a diameter of 112 μm. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a light spot having a diameter between 20-150 μm (*e.g.*, 112 μm) on the specimen in the modified apparatus of Reber *et al.*, in order to detect fluorescent members with a desired signal/noise ratio.

In regard to claim **45** which is dependent on claim 40, while Reber *et al.* also disclose (column 3, lines 39-47) the detection of fluorescent members, the modified apparatus of Reber *et al.* lacks that the fluorescent marker is Fluorescein. However, fluorescent markers such as fluorescein are well known in the art. For example, Ekins *et al.* teach (left column on pg. 1965) that fluorescein fluorescent markers (*e.g.*, FITC) are commercially available. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that the fluorescent members in the modified apparatus of Reber *et al.* is a known fluorescent member (*e.g.*, Fluorescein).

Response to Arguments

11. Applicant's arguments filed 2 December 2005 have been fully considered but they are not persuasive.

Applicant argues (last paragraph on pg. 9 to last paragraph on pg. 11 of remarks filed 2 December 2005) that Reber *et al.* fail to teach that the scanning control means provides the position signals as recited in claims 1 and 29 since it is unnecessary for Reber *et al.* to store or retrieve the position of the molecular receptors because the position of the molecular receptors is of no importance in Reber *et al.* In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, Examiner respectfully disagrees that the position of the molecular receptors is of no importance. Reber *et al.* state (column 5, lines 1-9) that "The processor 36 directs the operation of the positioning mechanisms 42, 44, 46, and 48, the data reader 34, the detector 38, and the data writer 40 to collect data from a plurality of sites and to write data to the device 20. The processor 36 can direct the operation of the aforementioned components to collect data in a sequential manner or in a random access manner. The processor 36 can include a computer or other like processing apparatus to direct the operation of the system". Thus the positioning devices (*e.g.*, 42, 44, 46, 48) of Reber *et al.* are used to position a variety of devices (*e.g.*, 34, 38, 40) at the plurality of sites. It is important to recognize that collecting data in a random access manner inherently implies that the site positions are known by processor 36 in order to selectively position the variety of devices (*e.g.*, 34, 38, 40) at the desired site for data collection.

Applicant also argues (last paragraph on pg. 12 of remarks filed 2 December 2005) that Gordon merely discloses re-scanning a specific region of interest to determine the presence of a particular material in a sample and cannot be used to obtain the position of the material in the sample or to view the image of the material in the sample at all which is different from placing the microscope at the position of the marked object as recited in claims 1 and 29 because Gordon's re-scanning cannot place any microscope at the position of the detected object. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, Examiner respectfully disagrees that Gordon does not teach obtaining an image of the material in the sample. Gordon states (column 6, lines 4-10) that "The system of FIG. 1 is adequate for obtaining an image of the disc surface, or a portion of that surface when the actual location of the portion itself is no significance. However, it may be desirable to be able to scan a selected area of the disc surface, for example where an ELISA has been carried out only in that region, or when it is desired to look again at a specific region of interest". Thus Gordon expressly teaches obtaining images of either the entire disc surface or a portion thereof. Further, Examiner respectfully disagrees that Gordon does not teach placing a detector at the position of the marked object. Gordon states (column 9, lines 28-33) that "Rather than scan the whole surface of the disc, the personal computer may be arranged to step the light source/detector arrangement over

the disc surface from one well to another. This is enabled by the precise position information obtained from the calibration marking and the disc edge". Thus Gordon expressly teaches stepping the light source/detector arrangement over the disc surface from one well to another using precise position information.

Applicant further argues (last three paragraphs on pg. 13 to first two paragraphs on pg. 14 of remarks filed 2 December 2005) that Virtanen fails to teach a microscope for viewing images of the marked objects and place the microscope at the position of the marked objects to allow a user to view the images of the marked objects via the microscope as recited in claim 1 and optically inspecting the object by viewing an image of the object via the microscope by a user as recited in claim 29. First it is noted that pending claims must be given their broadest reasonable interpretation consistent with the specification (MPEP § 2111) and the specification (pg. 14, lines 27-28) disclose that " ... the scanning control means may be adapted to place an automated microscope at the position of any desired target object". Thus microscope as recited in the claims is any of the known microscopes such as a scanning confocal laser microscope which forms a viewable image by scanning. Further in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, Examiner respectfully disagrees that the optical disk reader of Virtanen is used to detect the signal responsive moieties and cannot be used to view the image of the cells covered by the signal responsive

moieties. Virtanen states (column 48, lines 41-56) that "Although they have not previously been so recognized or described, optical disk readers are, in essence, scanning confocal laser microscopes. As such, they can be used, with proper software, to study the detailed structure of biological and other specimens. Cell counting and cell shape measurement are two examples of these applications. FIG. 33 depicts one geometry, based upon this principle, useful for detecting eukaryotic cells. The detection of eukaryotic cells in the present invention is best performed by attaching, directly to the device substrate surface, a first structure capable of recognizing and binding to the desired cells, such as an antibody. A second structure capable of recognizing and binding to the desired cells, such as a second antibody, is attached directly to the surface of a signal responsive moiety, such as a metal microsphere". Thus Virtanen expressly teaches a optical disk reader is a scanning confocal laser microscope. Virtanen further states (column 50, lines 1-3) that "By labeling the surface of cells relatively uniformly, their individual sizes and shapes can be measured by the optical disk drive functioning as a scanning confocal microscope". Thus Virtanen expressly teaches measuring cell size and cell shape by an optical disk drive functioning as a scanning confocal laser microscope. Therefore, the optical disk reader of Virtanen is used to view the image of the cells stained by e.g., signal responsive moieties (*i.e.*, the cells are made viewable by stains such as signal responsive moieties).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shun Lee whose telephone number is (571) 272-2439. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL

CONSTANTINE HANNAHER
PRIMARY EXAMINER